Date: September 19, 2007

To: NEHI Working Group, NSET Subcommittee, Nanotechnology EHS Research Needs

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RE: Public Comment, Prioritization of EHS Research Needs for Engineered Nanoscale Materials, Interim Document

My comments below are informed by my vantage as a principal investigator on an NSF-funded NIRT project on the social and ethical dimensions of agrifood nanotechnology, but they do not necessarily reflect the positions of my fellow co-PIs or of our agrifood nanotechnology project.

I may not have the exact numbers here, but as I recall, the 'Supplement to the President's 2006 Budget' (NNCO 2005) recommended overall NNI investments for 2005-06 of about $1.05 billion, with $82 million devoted to 'Societal Dimensions' including 'Environmental Health and Safety R&D' ($38.5 million) and 'Education and Ethical, Legal, and Other Societal Issues' ($42.6 million). So clearly, the NNI has invested strongly in support of research on the societal and ethical dimensions of emerging and applied nanotechnologies, and this investment is now bearing substantive dividends. Our agrifood nanotechnology project is but one of several 'societal dimensions' projects funded in this area, and we participate in a broader network of institutions constituting the Centers for Nanotechnology in Society. One of the key topics at the various events (conferences, workshops, meetings, etc.) sponsored by these projects concerns the integration of societal dimensions project outcomes and perspectives into the framing of future nano-related activities – from research and development to governance and broader societal understanding of and participation in these processes. So I'm somewhat surprised that there isn't a little more 'return on the federal investment' in societal dimensions reflected in the EHS Interim Document. This is alluded to somewhat in point two of the 'Principles' section, but no specific mention is made to the NSF-funded work in this area. I would think some explicit effort would have been granted toward the integration of the outcomes of projects funded previously through NSF, including but certainly not limited to the various societal dimensions projects. Was a formal effort ever made to consult the lead PIs on these projects? If so, then I apologize for my oversight; but if not, then that might have been helpful in framing that which came before to inform that which is now being proposed. But either way, the broader question still stands, namely, how shall societal dimensions be addressed or at least reflected in the prioritization of EHS research needs identified in the Interim Document?

I doubt there is any one answer to this question, and I'm certainly in no position to speak to the diverse perspectives developed across the various societal dimensions projects. I can, however, provide a few insights from our respective corner of the societal dimensions puzzle. I offer the following comments in the spirit of helping to integrate a bit of the social into the more overtly technical considerations currently reflected in the Interim Document.

1. Standards. The Interim Document acknowledges the relevancy of standards in EHS research, specifically with respect to 'Instrumentation, Metrology, and Analytical Methods.' The concept of 'standards' as an operational construct is something with which our institute (i.e., the Institute for Food and Agricultural Standards, or IFAS) has considerable experience, so not surprisingly my first comment draws heavily on this institutional experience.

Whereas 'standards' are generally considered to be convenient, neutral, and benign means for handling issues of technical compatibility and functionality, the concept also embodies broader strategic and societal dimensions. For example, if one thinks of 'social power' as the ability to set the rules that others must follow, then standards reflect a form of codified social power reflecting the interests of those with greatest social access to and influence within standards-setting processes. This includes the design and execution of the processes themselves. While many people recognize the importance of standards generally – i.e., in facilitating technical functionality, compatibility, common reference, supply chain interoperability, etc., -- social conflict often ensues when confronting the issue 'whose standards?' and perhaps more importantly, '*why* those standards and not others?' Are the justifications technical, scientific, economic, social, ethical, environmental, or some varying mix of these depending on the social context or sphere of economic activity in question? These kinds of questions will help to explicate the interplay between the technical and social aspects of EHS considerations in nanotechnology. Different stakeholders – industry, scientific, NGO, regulatory, labor, etc. – can be expected to appeal to different values in the standards they advocate, the standards outcomes of which will not only embody those interests but also serve to establish the 'rules of the game,' if you will, that all actors – including consumers – must subsequently follow (think Beta vs VHS). We see this playing out in nano today – definitional criteria, terminology, nomenclature, measurement; risk and hazard assessment; safe handling procedures; environmental fate; testing, etc., and international harmonization of these and other nanotechnology standards issues. There will be winners and losers in this 'standards game,' with considerable economic, political, and social advantage on the line. This appears all the more important given the NEHI Working Group is "…attempting to anticipate the commercial introduction of potentially harmful nanomaterials." One can even envision a proactive concern with environmental justice arising out of such considerations. We simply cannot afford to act as though EHS (or any other) research will proceed in a vacuum somehow removed from the social and strategic dimensions of these considerations. I personally do not believe the NEHI group is ignoring these things, but I would like to see considerably greater emphasis placed on them as the group further develops its EHS research priorities. I submit that 'standards' is one way – but by no means the *only* way – of integrating certain societal dimensions with technical considerations inherent in your EHS research activities.

Our Agrifood Nanotechnology Project recently convened an international standards workshop to address some of these issues (full report available at http://ifas.msu.edu/NSWorkshopReport.pdf). The workshop included participants representing a wide variety of perspectives, including business and industry, government regulatory agencies, labor groups, NGOs, trade associations, and standards-setting bodies, as well as numerous academic and technical disciplines. The purpose of the workshop was not to establish consensus around specific standards themes, but rather to chart a 'standards issues landscape' facing nanotechnology communities, including those pertaining directly to EHS. I don't want to oversell this process here, but I do think certain key outcomes have direct bearing on the framing of EHS research priorities, and in so doing provide a mechanism for integrating at least some societal dimensions into the Interim Document.

To that end, I respectfully offer the following six considerations abstracted from the executive summary of the standards workshop report:

> **Introduction**: Research, development and commercialization of nanotechnologies are moving forward in a period of uncertainty about elaboration of standards and regulation. This uncertainty poses differing opportunities and constraints for a variety of stakeholder

interests across numerous sectors of economic activity. The workshop and this report aim to identify key issues from a variety of stakeholder perspectives, and they point to those areas of inquiry for standards development that workshop participants believe are the most pressing. It should be noted that in the US context, the term 'standards' is often applied to both voluntary standards set by various private or and non-profit organizations as well as to mandatory public regulations set by government agencies. In contrast, in the EU voluntary standards are usually contrasted with government regulations. However, in recent years, in part as a result of increased global trade, the distinction between standards and regulations has become blurred. Many nominally voluntary standards have become de facto mandatory. In this document we follow the US usage, and the usage employed during the workshop, distinguishing where necessary between voluntary and mandatory requirements. Basic research is needed to determine the health, safety and environmental impact of emerging nanotechnologies. Without such data, it is difficult to move the standards-setting process forward. Additionally, common nomenclature and cooperative frameworks need to be established early in the process of technology development. These are overarching issues. The remainder of our discussion and recommendations cluster around five themes.

A. Timing and Standards-Setting. Standards for nanotechnology need to be developed for all of the stages in the life cycle of the products (research, production, products, waste, etc.). Research into nanotechnology is already moving forward under existing standards for lab safety, but development of nanotechnology-specific standards is needed. The production phase is also likely to be a high-risk point. Agencies experienced with worker health and safety should, therefore, be engaged early. Moreover, standards to regulate consumer products are also lacking and there is disagreement about whether new legislative authority is needed to guide the elaboration and implementation of such standards. Finally, standards for nanotechnology lab waste, production waste, and end-of-product-life waste raise new questions. Both private and governmental actors should collaborate to address these issues. We urge prioritization of these areas based on the most current safety and risk data, as well as adequate funding for risk analysis to ensure that standards-setting is able to keep pace with research and development.

B. Product vs. Process Standards. Nanotechnology raises questions about where within the lifecycle of a product it makes most sense to place various standards and regulations. Research on nanotechnology risk assessment and analysis will be useful in determining the most efficacious way to implement these standards and regulations. Different government agencies have different mandates in this regard and this will likely have a large impact on whether we have product or process standards in any given product or sector. We encourage interagency cooperation to create the most effective standards. Agreement is needed on the goals of the standards to clearly decide whether it makes more sense to regulate products or processes.

C. International Harmonization. The US, EU and Japan are all investing significantly in nanotechnology development. Given the global economy, it is certain that intermediate nanotechnology products and finished goods will be marketed globally. This calls for at least limited international harmonization of standards and regulations. Dialogue and cooperation among diverse stakeholders is needed to determine which standards should be harmonized and what the commitments to international enforcement should be made. Ultimately, we recognize that the debate over international harmonization of standards for any technology

is a debate about national difference in concern and prioritization of worker health and safety, environmental protection, economic competitiveness, etc. A certain level of national autonomy in these realms is reasonable.

D. Integration of Operational Standards. The development of effective nanotechnology standards will require that standards-setting agencies that have not historically worked together begin to do so. Mechanisms for interagency cooperation should be primary goals in this process. Achieving information sharing and effective interagency communication will serve as first steps towards more effective standards-setting. Lawmakers can assist in this process by providing adequate funding and clear authority to integrate agency mandates. Careful consideration is needed, however, in choosing an appropriate model. Top-down models should be avoided, and promising bottom-up models explored. The Coordinated Framework for Biotechnology also provides a possible, though limited, initial model. Where appropriate, integration with the private sector is also recommended, as some private sector bodies now act as de facto standards-setting bodies. ISO, Codex, and the IPPC offer good models for this kind of integrative approach.

E. Participation and Transparency in Standards-Setting Processes. It was once seen as acceptable for scientific experts, government bureaucrats and business interests to debate and establish standards with little or no input from the larger public. This approach has justifiably been called into question in recent years. In the future, we expect to see more attempts at public participation in the standards-setting process than has previously been the case. The type and nature of public participation is largely undefined, and it is this area that needs most attention. For public participation to be seen as legitimate in the eyes of the public, careful attention needs to be paid to identifying potentially affected groups and engaging them in meaningful ways in the standards-setting process. Several possible models for making this a reality were discussed. Standards-setting bodies need to review and learn from models that have been more successful than the typical "public meetings" model common in the US regulatory system.

2. Labeling. This comment relates back to the 'product vs. process standard' issue discussed above. I want to draw attention to the potential backside consequences of various EHS standards developed now. Consider, for example, the hypothetical case of 'nano bread.' What makes it nano? On one hand – the 'product' hand – we might envision standardized tests for the presence of engineered nano-particles of one purpose or another in the bread, which, if present, may constitute it as 'nano bread,' possibly even requiring an FDA label to that effect. On the other hand – the 'process' hand – engineered nano-particles may not be present in the bread itself but rather in the production and/or processing of the wheat used to make the bread. Will EHS standards be primarily product or process based, and what implications might this have for the constitution and potential labeling of some 'thing' as 'nano?' Thinking up front about these issues now would provide an additional opportunity to integrate social concerns into future EHS research activities and priorities. Again, whose standards will count as this process moves forward, and (how) will diverse voices be factored into the establishment of the standards ultimately promulgated and enforced?

3. Public Participation, Risk Communication/Mgt. The Interim Document identifies potential relationships between risk management and communication, and discusses five broad research needs within that category. The fifth of these needs includes the development of "...effective methods for communicating [to potentially affected populations] information on hazards from and potential

exposure to nano-materials…" In general, I support the development of more effective methods for communicating hazard and risk information to potentially affected populations, but my concern here is with the use of the word "to." As you know, the NNI convened a workshop last year to address issues of public participation in nanotechnology, including models of engagement and risk communication. Many of the participants were members of various 'societal dimensions' projects. People often come away from such events having heard what they wanted to hear, and my observation here may be no exception to this, but as I recall, one of the common themes emerging from the workshop was the dire need for models of engagement that not only communicate *to* the public, but *with* the public as well. This may seem like a minor semantical issue, but it presents great opportunity for dialogue concerning what might be called 'social vectors of risk exposure,' specifically those pertaining to the "…use of consumer products containing engineered nanomaterials." To some extent, this task turns risk identification and communication on its head, for it is the "potentially affected populations" – the citizen/consumers of various publics – that hold conceptions and perceptions of risk that directly influence how they will interact with nano processes and products, which of these are socially acceptable (i.e., and thus tenable from risk conception/perception perspectives) and in what social contexts, and the kinds of potential exposure pathways this opens up. And it is vital that methodologies be developed through which such *public* conceptions and perceptions of nano-related risks can be communicated back 'upstream' to inform those who are developing the nano-science, -processes, -products, and their associated regulations and standards[1]. In my 20+ years experience in this field, this is the 'stuff' of societal dimension. Such methodologies, as developed, will not replace but rather supplement the formal risk assessment studies alluded to in the Interim Document; they will provide an additional mechanism for integrating societal dimensions with the more overtly technical dimensions of nano exposure assessment and risk management research. Point #3 in the 'Health and Environmental Exposure Assessment' category comes close to this, but I see no explicit discussion of multi-path risk communication there nor in the 'Risk Management' category which follows it. Such models are presently being developed in this direction, for example, we presented at the NNI public participation workshop on integrating ethnographic risk perception models with the CSREES Extension System, and I know others in the 'societal dimensions' project crowd are working in similar directions. That is to say, EHS research needn't start from scratch in this area, but I would like to see more explicit attention devoted to these issues in the Interim Document.

In closing I would like to thank the NEHI Committee et al., for its significant time and effort in producing the EHS Interim Document and for its consideration of public comments made on its behalf. I wish you the best of goodwill in this challenging task.

Respectfully Submitted,

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[1] In accordance with comment 1.E., above, the same holds true for public participation in the development of nanotechnology standards generally, as well as in the development of standards for nano-specific risk identification, assessment, communication, and management.